REMARKS

Pursuant to the entry of this amendment, claims 1-24 are pending in this application, with claims 6-19 being withdrawn from consideration subject to a restriction requirement. Accordingly, claims 1-5 and 20-24 are presently under consideration. Regarding the specific amendments to the claims:

Claim 1 has been amended to clarify that the claimed composition is formulated for topical administration to a patient in need thereof. Support for this amendment is found in the specification as originally filed, particularly at p. 12, lines 13-27. Claim 1 has been further amended specify that the extracted lipid fraction is primarily composed of unsaturated C18 fatty acids selected from the group consisting of linoleic acid, oleic acid, and linolenic acid. Support for this amendment is found in the specification as originally filed, particularly at p. 4, lines 4-17 and Table 1 on p. 5. New claim 23, depending from claim 1, further specifies that the extract lipid fraction comprises about 51 to about 61% by weight linoleic acid. Support for this amendment is found in the specification as originally filed, particularly at p. 4, lines 8-10. New claim 24, also depending from claim 1, further specifies that the extract lipid fraction comprises about 20 to about 25% oleic acid. Support for this claim is found in the specification as originally filed, particularly at p. 4, lines 10-12. Applicant respectfully submits that the claims so amended define a composition distinct from that found in the prior art. Applicant further submits that no new matter has been added.

Accordingly, Applicant submits that the instant response renders moot the outstanding claim rejections and places the instant application in condition for allowance. Further to this position, Applicants submit the following remarks:

Rejections under Section 103 - Haresh et al.:

Claims 1-5 and 20-22 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Haresh et al. (1989). According to the Examiner, Haresh et al. disclose an oily extract of *N. sativa* analogous to that described and claimed by Applicant. While they do not specifically teach the incorporation of a pharmaceutical carrier, the Examiner submits that one would have been motivated to add a carrier, such as alcohol or another oil, for example, to dilute the oil to a desired concentration or to ease the dispersement of the oil as needed. As

to the specifically claimed components and ratios, the Examiner states that it is well known in the art that two plants of the same species will rarely comprise the same exact endogenous phytochemical ratios. Absent evidence to the contrary, she submits that the Haresh oil and the oil of the pending claims would be the same or so similar that no discernable differences can be made.

Applicant respectfully disagrees with the Examiner's characterization of the prior art. Furthermore, Applicant respectfully submits that the instant amendment to claim 1, from which claims 2-5 and 20-24 all directly or indirectly depend, renders moot the instant rejection.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See M.P.E.P. § 2142, 2143.

Importantly, the initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The mere fact that a reference can be modified does not render the resulting modification "obvious" unless the prior art also suggests the desirability of the modification. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Similarly, although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432. In other words, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time

the claimed invention was made" is not sufficient to establish a prima facie case of obviousness without some objective reason to modify or combine the teachings of the reference(s). *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000).

In this case, the Examiner suggests that, given the similar extraction processes, the resulting *N. sativa* extracts would be the same. However, as discussed at p. 212, the Haresh extract is primarily comprised of saturated fatty acids, namely palmitic fatty acid (12.79%) and stearic acid (7.19%). Unsaturated C18 fatty acids, such as linoleic acid, oleic acid, and linolenic acid, constitute only a very small percentage of the extract (e.g., 7.29% oleic acid and 4.09% linoleic acid). This point is reiterated at p. 213 wherein Haresh correlate a low content of C18 fatty acids with negative activity (i.e., a low insect growth regulating activity). Haresh et al. then attempt to explain the high juvenile hormone activity of *Nigella sativa* as perhaps resulting from the presence of essential oil (e.g., a volatile or ethereal oil). See page 214.

Conversely, the *N. sativa* L. lipid fraction extract of the present invention is primarily composed of polyunsaturated fatty acids ("about 73 to about 92% by weight"; specification at p. 4, lines 4-5), more particularly unsaturated C18 fatty acids such linoleic acid ("about 51 to about 61% by weight": specification at p. 4, lines 8-10), oleic acid ("about 20 to about 25% by weight": specification at p. 4, lines 10-12), and linolenic acid ("about 0.7 to about 2% by weight": specification at p. 4, lines 12-13). Thus, contrary to the Examiner's suggestion, the oily extract of the prior art is indeed "discernibly different" from the *N. sativa* L. extract presently claimed.

While not wishing to be bound by theory, Applicant believes this disparity in composition may arise from the use of a divergent extraction process and/or contamination. With respect to the latter, commercially available *Nigella sativa* seeds are frequently contaminated with other seeds as well as other species of Nigella, for example *Nigella damascena*. Conversely, the instant invention utilizes unadulterated *Nigella sativa* L. seeds, thereby giving rise to a pure *Nigella sativa* L. extract having unique component ratios, which in turn confer unique therapeutically beneficial properties. Accordingly, the resulting lipid fraction extract of the instant invention is fundamentally different from the previously described *N. sativa* extracts of the prior art.

With respect to the former, whereas the seed oils of Haresh et al. "were soxhlet extracted using petroleum ether" (see bottom of p. 209), the oily extract of *N. sativa* L. of the instant invention is preferably obtained through successive extraction "in a percolator until exhaustion with various solvents in order of increasing polarity. . .in order, petroleum ether. . .hexane, ether, chloroform, ethylacetate, acetone, ethanol, methanol, and water." See Example 1 of the specification as originally filed, particularly p. 14, lines 8-11. Applicant respectfully submits that this successive extraction process, in contrast to Haresh's soxhlet extraction process, yields an *N. sativa* L. oil having a high content of unsaturated C18 fatty acids. Accordingly, the resulting *N. sativa* L. extract of the instant invention is fundamentally different from the *N. sativa* extracts identified previously in the art.

Applicant further submits that Haresh et al. fail to disclose or suggest a composition formulated for topical administration to a patient in need thereof as specified by claim 1 as amended herein. Specifically, Haresh et al. describe their *N. sativa* extract as a potential pesticide. Given the obvious toxicity issues, one skilled in the art would clearly not have been motivated to formulate the *N. sativa* extract described by Haresh et al. for topical administration, in a form suitable for patient contact. Since clear indications of motivation are missing, the motivation to modify can only arise from Applicant's own disclosure and not from the prior art references themselves. Accordingly, the Examiner's conclusion of obviousness in this case can only be based on improper hindsight reasoning, constituting an *ex post* analysis that utilizes knowledge gleaned from Applicant's disclosure and not from the prior art. As such, the rejection is improper and should be withdrawn.

Thus, for the reason set forth above, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-5 and 20-22 under 35 U.S.C. § 103(a) as being obvious in view of Haresh et al.

Rejections under Section 103 - Kandil:

Claims 1-5 and 20-22 stand rejected under 35 U.S.C. § 103(a) as being obvious in view of Kandil (US 2002/0132019 A1). According to the Examiner, Kandil discloses an oily extract of *N. sativa* analogous to that described and claimed by Applicant. While he does not specifically teach the inclusion of a pharmaceutical carrier or any specific use for the oil, the

Examiner submits that one would have been motivated to add a carrier, such as water, so as to dilute the oil for further testing.

Applicant respectfully disagrees with the Examiner's characterization of the prior art. Applicant further submits that the instant amendment to claim 1, from which claims 2-5 and 20-24 all directly or indirectly depend, renders moot the instant rejection.

In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention "not novel" or "anticipated" within section 102 or "obvious" in the context of section 103, the stated test is whether a reference contains an "enabling disclosure". *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating or obviating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

In this case, claim 1 as presently pending requires a composition formulated for topical administration to a patient in need thereof, such composition comprising a lipid fraction extracted from *N. sativa* L. seeds composed primarily of unsaturated C18 fatty acids such as linoleic, oleic, and linolenic acids. Applicant respectfully submits that the Kandil 2002 publication fails to provide an enabling disclosure of the *N. sativa* L. extract required by the pending claims. Specifically, Kandil 2002 describes the intermediate lipid fraction as a "petroleum ether or hexane extract". See Example 1 at p. 12, lines 10-11. Given the teachings of Haresh et al., one would expect such an extract to be primarily comprised of palmitic acid, a C16 saturated fatty acid. Conversely, the oily extract of *N. sativa* L. of the instant invention is preferably obtained through successive extraction "in a percolator until exhaustion with various solvents in order of increasing polarity. . .in order, petroleum ether. . .hexane, ether, chloroform, ethylacetate, acetone, ethanol, methanol, and water." As noted above, this distinct extraction process yields an extract with unique properties, namely an *N.*

sativa L. oil having a high content of unsaturated C18 fatty acids. Accordingly, given that the resulting *N. sativa* L. extract of the instant invention is unexpectedly and fundamentally different from the oily extract described by Kandil in 2002, the Kandil 2002 publication cannot be considered to be an enabling disclosure of the invention now claimed nor can it serve to anticipate or render obvious the invention of the pending claims.

Furthermore, claim 1 as presently pending requires a composition formulated for topical administration to a patient in need thereof. As the Examiner correctly notes, Kandil 2002 fails to disclose or suggest any pharmaceutical use, much less a topical use, for the "lipid (oily) fraction". In fact, the only utility afforded to the lipid fraction is as an intermediate in the process for producing the desired final product, namely in the context of isolating the unsaponified fraction composed of total sterols and volatile oils. Accordingly, there is no teaching or suggestion in Kandil 2002 to isolate the lipid intermediate and formulate it for topical administration, for example, as "an ointment, cream, gel, powder, balm, lotion, liquid, spray, or aerosol or as the active ingredient in a transdermal patch" as specified in claim 2. Since clear indications of motivation are missing, the motivation to modify can only arise from Applicant's own disclosure and not from the prior art references themselves. Accordingly, the Examiner's conclusion of obviousness in this case can only be based on improper hindsight reasoning, constituting an *ex post* analysis that utilizes knowledge gleaned from Applicant's disclosure and not from the prior art. As such, the rejection is improper and should be withdrawn.

Thus, for the reason set forth above, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 1-5 and 20-22 under 35 U.S.C. § 103(a) as being obvious in view of Kandil.

CONCLUSION

In sum, Applicant submits that the claims herein set forth a novel, non-obvious invention. Accordingly, Applicant submits that claims 1-5 and 20-24 as amended herein are in condition for allowance and respectfully petition for an early notice of allowance.

The outstanding Office Action set a three-month shortened statutory period for response. Applicant submits herewith a Petition for a Two-Month Extension of Time, extending the deadline for response to on or before **November 1, 2006**. Accordingly, Applicant submits that this response is timely and no additional fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, she is invited to contact the undersigned.

Respectfully submitted,

Date: 11/a/06

By _____

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